

# Federal Advisory Committee (FAC) Membership Balance Plan

Please read the Federal Advisory Committee Membership Balance Plan Guidance prior to completing this form

<b>(1) FEDERAL ADVISORY COMMITTEE NAME</b> <i>State the legal name of the FAC</i>
The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests
<b>(2) AUTHORITY</b> <i>Identify the authority for establishing the FAC</i>
The authority for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) is section 1834A(f)(1) of the Social Security Act (42 U.S.C. 1395m-1), (the Act) as amended by section 216 of Public Law 113-93—April 1, 2014.
<b>(3) MISSION/FUNCTION</b> <i>Describe the mission/function of the FAC</i>
<p>The Panel may advise the Secretary, Department of Health and Human Services (HHS), and the Administrator, Centers for Medicare &amp; Medicaid Services (CMS), on the following:</p> <ol style="list-style-type: none"><li>1) the establishment of payment rates under section 1834A of the Act for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test; and</li><li>2) the factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests.</li></ol> <p>In addition, the Panel will provide recommendations to the Secretary and the Administrator of CMS under section 1834(A) of the Act.</p> <p><b>DESCRIPTION OF DUTIES</b></p> <p>The Panel may advise on the following issues:</p> <ul style="list-style-type: none"><li>• Calculation of weighted median of private payor rates for clinical diagnostic laboratory tests.</li><li>• Phase-in of reductions in Medicare payment rates from private payor rate implementation.</li><li>• Application of market rates to establish Medicare payment rates.</li><li>• Evaluation and designation of tests as advanced diagnostic laboratory tests.</li><li>• Whether to use crosswalking or gapfilling to determine payment for a specific new test.</li><li>• The factors used in determining coverage or payment processes for new clinical diagnostic laboratory tests.</li></ul>

#### **(4) POINTS OF VIEW**

*Based on understanding the purpose of the FAC,*

- (a) describe the process that will be used to ensure the committee is balanced, and identify the categories (e.g. individual expertise or represented interests) from which candidates will be considered;*
- (b) consider indentifying an anticipated relative distribution of candidates across the categories; and*
- (c) explain how a determination was made to appoint any individuals as Special Government Employees or Representative members*

The Panel shall consist of an appropriate selection of individuals with expertise in issues related to clinical diagnostic laboratory tests, which may include, molecular pathologists, laboratory researchers, and individuals with expertise in laboratory science or health economics, with regard to issues related to the development, validation, performance, safety, and application of such tests.

The Panel is technical in nature, and members shall be selected based on their experience with clinical diagnostic laboratory tests.

Panel membership shall be balanced between individuals with different experiences and expertise in issues related to clinical diagnostic laboratory tests, which may include, molecular pathologists, laboratory researchers, and other individuals with expertise in laboratory science or health economics, with regard to issues related to the development, validation, performance, safety, and application of such tests.

Members of this panel may include special government employees with expertise in clinical diagnostic laboratory services.

Prior to each meeting, the representatives are reminded of ethical obligations and how to handle potential conflicts of interest. Any Panel member with a potential conflict of interest on a topic presented for recommendation during the Panel meeting is asked to excuse himself from voting on the Panel recommendation.

#### **(5) OTHER BALANCE FACTORS**

*List any other factors your agency identifies as important in achieving a balanced FAC*

Appointments shall be made without discrimination on the basis of age, race, gender, sexual orientation, disability, color, national origin, HIV status, and cultural, religious, or socioeconomic status. During the nomination process, the committee is reviewed in totality for balance with regard to geographic location and representation of female and minority interests and perspectives.

#### **(6) CANDIDATE IDENTIFICATION PROCESS**

*Summarize the process intended to be used to identify candidates for the FAC, key resources expected to be tapped to identify candidates and the key persons (by position, not name) who will evaluate FAC balance. The summary should:*

- (a) describe the process*
- (b) identify the agency key staff involved (by position, not name)*
- (c) briefly describe how FAC vacancies, if any, will be handled by the agency; and*
- (d) state the membership term limit of FAC members, if applicable*

A Notice is prepared by the Designated Federal Officer (DFO) and published in the Federal Register to solicit nominations for any open positions. Nominees are solicited from clinical laboratory test manufacturers and other organizations or individuals having expertise in clinical diagnostic laboratory tests or genetic testing and can be nominated by an organization, individual, or self-nominated.

Once the nomination period closes, the DFO will screen the nominees for their qualifications for the Panel. The nominees shall provide various information, for example, educational credentials, current job title and position, professional affiliation, experience with the clinical diagnostic

laboratory tests or genetic testing environments (a minimum of five years experience in their area of expertise is required), among other factors.

A list of best qualified nominees possessing the relevant expertise is then presented by the DFO to a panel of CMS employees, including managers and medical officers. The CMS panel will then select nominees with the most comprehensive experience with clinical diagnostic laboratory tests or genetic testing. In selecting nominees, the CMS panel will also consider factors needed to keep the balance of the Panel. The CMS panel will narrow the number of nominees to the number of openings for the Panel. This short list of nominees is presented to the Director and Deputy Director of the Center for Medicare within CMS for input. The top nominees will be contacted for interest and availability. If approved by the Director of the Center for Medicare, he or she extends formal letters of invitation to serve on the Panel.

The membership structure is outlined in the committee charter and describes the desired expertise needed.

The responsible DFO must keep abreast of term ending dates and have appointments to fill vacancies ready in advance. Approximately nine to twelve months before a vacancy is to occur, the DFO works with appropriate officials to discuss candidates and mechanisms to seek additional nominations. The DFO is responsible for ensuring that vacancies are filled promptly, terms remain staggered as provided in the committee charter, and, to the extent possible, full slates of nominees are submitted for vacancies.

The Director of the Center for Medicare makes the final decision about who will serve on the committee.

Panel members will serve a term of up to three years. A member may serve after the expiration of his/her term until a successor has been sworn in.

A Panel member selected to replace another Panel member who has resigned prior to the end of his or her term, shall serve for the balance of the original Panel members' term.

#### **(7) SUBCOMMITTEE BALANCE**

*Subcommittees subject to FACA\* should either state that the process for determining FAC member balance on subcommittees is the same as the process for the parent FAC, or describe how it is different*

*\*This is relevant to those agencies that require their subcommittees to follow all FACA requirements*

The process that will be used to determine advisory committee membership balance for the Panel is also used for any Panel subcommittees.

#### **(8) OTHER**

*Provide any additional information that supports the balance of the FAC*

The Panel reflect a balance membership for the following characteristics: gender (7 female, 8 male); geographic regions (12); degree/specialty (2 MD/PhDs; 5 PhDs; 6 MDs) and employment (industry, private, public & academia).

#### **(9) DATE PREPARED/UPDATED**

*Insert the actual date the Membership Balance Plan was initially prepared, along with the date(s) the Plan is updated*

Original preparation date: February 1, 2017

Updated date: March 13, 2017